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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/827,172

04/19/2004

James Dobbie

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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11/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/827,172	Applicant(s) DOBBIE, JAMES	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-21-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 10-29-07 is acknowledged. The traversal is on the ground(s) that the term distinct means that two or more subjects as disclosed are related --- but are capable of separate manufacture, use or sale as claimed, and are patentable over each OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02): 1. Separate classification 2. Separate status in the art; or 3. Different field of search. This is not found persuasive because the lamellar bodies can be made by different methods such as hydration of the lipid film or reverse phase ethanol injection technique or even isolated from lung tissue as the prior art submitted by applicant indicates (See Post et al in Experimental lung Research, 1982). With regard to the classification, the examiner point out that lamellar bodies are classified in class 424, subclass 450 whereas the methods are classified in surgery, class 604

The requirement is still deemed proper and is therefore made FINAL

Claims included in the prosecution are 1-15.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meets and bounds of 'lamellar bodies' and 'linear macromolecules' in claims 1 and 7 are unclear.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72277 of record.

WO teaches liposome compositions containing phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol and cholesterol in claimed amounts (pages 5, 6, 15-17 and claims, 7 and 9 in particular). The intended use has no significance in the composition claims.

4. Claims 1, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz (Journal of Lipid Research, 1991) of record or Post (Experimental Lung Research, 1982) or Nemechek (1997) of record or King et al (Am J Physiol Lung Cell Mol physiol. 2002).

Schmitz teaches lung surfactant compositions containing lamellar bodies (Abstract and Table 2). Similarly Post, and King disclose lamellar bodies containing instant components (Tables 3 and 4 of Post; L289, the paragraph bridging columns 1 and 2 of King).

Nemechek teaches the use of nebulized bovine lung surfactant for experimentally induced Otitis media (page 476, col. 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al (Am J Physiol Lung Cell Mol physiol. 2002).

King discloses a composition containing lamellar bodies. The composition contains phosphatidylcholine, PG, PS, PI, sphingomyelin and cholesterol. King discloses the amounts of these components in molar ratios (L289, the paragraph bridging columns 1 and 2) and not weight ratios. King also discloses the PC, PG, PI, sphingomyelin and PS in natural lung surfactants on col. 1, first paragraph on the same page. Assuming that the amounts of the components in the synthetic lamellar bodies of King are different weight percentages, since the purpose of King is to study the viscosities of various synthetic surfactant compositions resembling natural lung surfactants, it would have been obvious to vary the amounts to obtain the best possible combination resembling the natural surfactant. It should be pointed out that the sphingomyelin amount in natural surfactants taught by King is only 2 %

Art Unit: 1615

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemechek (1997) by itself in combination with WO 01/72277 or Nemechek, in combination with King cited above and WO 01/72277.

Nemechek teaches the use of nebulized bovine lung surfactant for experimentally induced Otitis media (page 476, col. 2). Although Nemechek does not teach the amounts of PC, PI, PS, PG, sphingomyelin and cholesterol specifically, the reference of King teaches bovine lung surfactant contains approximately the same claimed amounts except for sphingomyelin, which is only 2 % (see paragraph 1, col. 1, L278).

The teachings of WO have been discussed above. WO further teaches That sphingomyelin provides flexibility and softness to lamellar bodies (page 16, lines 30-34). The amounts of sphingomyelin taught are 19 % (claim 7).

To increase the percentage of sphingomyelin in Nemechek would have been obvious to one of ordinary skill in the art since sphingomyelin provides softness and flexibility to lamellar bodies as taught by WO.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ

Art Unit: 1615

619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 11-13 and 15 of copending Application No. 10/678,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications recite the same lamellar body compositions with overlapping percentages for individual components and therefore, instant claims are anticipated by the claims in the copending application. Instant claim 1 is generic with respect to the individual components and it would have been obvious to one of ordinary skill in the art to vary the components in the lamellar bodies (liposomes) with a reasonable expectation of success since the use of the liposomes depends upon the disease to be treated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose

Art Unit: 1615

telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK